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[No.4350—ST-BT-MISC-0016/2024/ST.]

SCIENCE & TECHNOLOGY DEPARTMENT

RESOLUTION

The 6th September, 2024

SUB: OPERATIONAL GUIDELINES FOR QUALITY CERTIFICATION ASSISTANCE UNDER ODISHA BIOTECHNOLOGY POLICY- 2024.

*(Science & Technology Department Resolution No - 393-ST-BT-MISC-0026/2022/ST.,
dated the 25th January, 2024) (See Para 4.2.13 of Odisha Biotechnology Policy, 2024)*

1. **Short Title:**—Operational guidelines for providing assistance for Quality Certification under Odisha Biotechnology Policy, 2024.
2. **Extent:** —It shall extend to the whole of the State of Odisha.
3. **Commencement:**—It shall come into force from the “Effective Date” of Odisha Biotechnology Policy 2024 i.e. dated 25th January, 2024.
4. **Terms and Expressions:**—Terms and expressions used in this operational guideline, but not specifically defined / explained here, shall have the same meaning as in Odisha Biotechnology Policy, 2024.
5. **Definitions / Explanations:** –
Nationally and internationally recognized institutions - Certification Body or Certification Registrar accredited by National / Regional Accreditation Bodies or by International Accreditation Forum.
6. **Policy Provisions:**— (4.2.13 of OBP-2024)
Quality Certification Assistance subject to maximum limit of Rs.25 lakh for obtaining quality certifications from recognised institutions during the policy period.
7. **Eligibility:** –
 - a. The scheme shall be open to Biotechnology units/Start-ups/Institutes engaged in product/process development operating in the state of Odisha with a healthy financial track record.

- b. The eligible Biotechnology units/Start-ups/Institutes can avail this assistance up to maximum limit as mentioned in the policy provision.
- c. Eligible Biotechnology units/Start-ups/Institutes that has availed this assistance from any other schemes of the State Government/ Government of India/ Government agencies shall be entitled only for the differential amount of benefit.

8. Eligible costs of assistance shall include: –

- a) Cost of application form and or application fees, assessment fees, processing charges, and all other associated costs / charges / fees, paid to the competent Registering Authority.
- b) The total amount of assistance under these rules shall be limited to Rs.25 lakh for a unit. If any unit obtains quality certificate for more than one product during the operative period of this policy, the assistance shall be available for each quality certificate separately subject to an overall cumulative limit of Rs.25 lakh (Twenty-five lakh).
- c) ISO certification and Renewal of quality certificate is not covered in the scope of this scheme.
- d) Quality Certificate include – NABL, CAP, FSSAI, CDSCO, WHOGMP, International regulatory certifications and related certifications as deemed valid by the authorities.

9. Time frame for filing application:–

- a. The eligible Biotechnology units/Start-ups/Institutes shall submit its claim in the prescribed form within one year from the date of obtaining quality certification.
- b. Application in the prescribed form received after the due date / incomplete in any respect shall be liable to be summarily rejected.

10. Procedure: -

- 1. Biotechnology units/Start-ups/Institutes satisfying the eligibility criteria shall file application in the prescribed form appended to this operational guideline at **Annexure -'A'** along with copies of all relevant documents as mentioned in the Checklist at **Annexure -'B'** to the Director, Biotechnology within the prescribed time limit.

2. Copies of the documents as indicated in the checklist shall be self - attested by Proprietor / Promoter/ Managing Partner / Managing Director / Authorized Signatory.
3. Applications received will be placed before the Scrutiny Committee consisting of the following members for screening and recommendation:

Sl. No	Designation	Position
1	Director, Biotechnology, Science & Technology Dept.	Chairperson
2	Representative from Industry Dept.	Member
3	Technical expert from Biotechnology Industry	Member
4	Technical expert from Biotechnology R&D Institute	Member
5	Expert on Quality Certification	Member
6	Deputy Director, Biotechnology, Science & Technology Dept.	Member Convener
7	Any other Expert member as required (Sector Specific)	Member

4. If required, Director Biotechnology may refer the proposal or obtain technical opinion from any other Govt. / Semi Govt./ Certified Private Organization within the country or abroad in the matter prior to sanction of assistance.

11. Sanction & Disbursement:–

- a. The recommendation of the Scrutiny Committee, shall be placed to the Govt. for due approval.
- b. After obtaining due Government approval, Director Biotechnology, Science & Technology Department, shall issue the sanction order to the Biotechnology Unit/Start-ups/Institutes within 15 days.
- c. The assistance shall be disbursed online through DBT to the approved Biotechnology Unit's bank account, subject to receipt of the indemnity bond.
- d. Disbursement will be made as per the availability of funds.
- e. The beneficiary unit shall furnish the utilization certificate **as per OGFR guidelines, 2023** to the Science & Technology Department after receipt of the assistance.
- f. An output report on the quality certification in terms of enhanced productivity, quality output, manpower engaged, profitability, etc. shall be submitted by the

beneficiary Biotechnology unit to Science & Technology Department, Odisha once in each year for a period of 3 years from the date of sanction of the assistance.

12. Recovery on Quality Certification Assistance:–

In the following events or circumstances, assistance on quality certification received by a Biotechnology unit shall be recoverable from it within a period of one month from the date of an order issued to such effect by the Director Biotechnology:

- a. In case a Biotechnology Unit has availed of this assistance by misrepresentation, fraud or by furnishing false & misleading information or by suppressing facts/ materials or disbursed in excess of the amount actually admissible for whatsoever reason.

13. Miscellaneous: –

- a. Any change in facts or circumstances affecting the eligibility of the unit shall be immediately intimated in writing to the Science & Technology Department, Odisha by the unit.
- b. Time limit prescribed in this guideline is of working days only.
- c. Wherever, any doubt arises regarding implementation of these rules, the same shall be referred to Government of Odisha in the Science & Technology Department whose decision shall be final and binding on all the parties.
- d. If the Quality Certificate is revoked by the authority for any reason the unit shall immediately intimate in writing to the Science & Technology Department.

By Order of the Governor
CHITHRA ARUMUGAM
Principal Secretary to Government

**APPLICATION FOR SANCTION AND DISBURSEMENT OF ASSISTANCE FOR
QUALITY CERTIFICATION UNDER PROVISIONS of ODISHA BIOTECHNOLOGY
POLICY- 2024.**

*Application received after the due date / incomplete in any respect shall be liable for
rejection)*

(Strike out whichever is not applicable)

From

M/s. _____

At _____

PO _____

Sub-Division _____

Dist. _____

(Location of the Biotechnology Unit)

To

The Director, Biotechnology

Science & Technology Department, Govt. of Odisha

7th Floor, Kharvela Bhawan

Bhubaneswar-751001

Sub: Sanction & disbursement of assistance for Quality Certification under OBP- 2024

Sir,

In accordance with the provisions laid down in Odisha Biotechnology policy, 2024 and its operational guidelines, the claim for assistance Quality Certification is submitted with following particulars.

1	Category of the Unit		:	
	A	MSME / Large / Mega Units	:	
	B	(i) Migrated Unit as defined in Odisha Biotechnology policy, 2024	:	
		(ii) E/M/D as defined as defined in Odisha Biotechnology policy, 2024	:	
	C	Institute		

2	Address of Registered office	:				
3	Type of organization (Proprietorship / Partnership / Co-operative / Private Limited / Public Limited)	:				
4	Name of Proprietor / Managing Partner / Managing Director / Authorized Signatory	:				
5	EM-II / IEM / I L No./Production Certificate and date	:				
6	Items of manufacture / activity	:	Original			
			Item	Quantity	Value	
			After expansion / modernization / diversification			
			Item	Quantity	Value	
7	Date of commencement of production	:	Original-			
			E / M/ D-			
8	Date of first fixed capital investment for New Biotechnology Unit (i.e., plant & machinery and balancing equipment.)	:				
9	Date of first fixed capital investment for E/M/D of Existing Biotechnology Unit.					
10	Total Capital investment	:	Original	E/M/D	Total	
	(Head-wise & specify investment in Laboratory / R&D Lab)					
	a.					
	b.					
	c.					
	d					

11	Name of the Financial Institution (s) / Bank(s) Specify the date of sanction & amount of term loan / working capital loan	:	
12	Whether loan has been availed from FI / Banks for the purpose of obtaining quality certification, if so specify-		
	a. Name of FI/Bank		
	b. Amount of loan availed		
13	Name the products or activities for which quality certificate has been obtained.		
14	Name & address of the Registration Authority Authorities issued Certificate(s)		
15	Certificate No. with date (copy to be submitted)	:	
16	Amount of expenditure incurred for obtaining Quality Certification/ vouchers /receipt etc. be submitted with a statement)		
17	Present claim for assistance		
18	Details of assistance sanctioned / availed from any State Govt. or the Central Govt. (GoI) or any Financial institutions of the country or abroad, in this regard with sanction order no & date		
19	Differential amount of claim		

I ,Mr./Ms. _____ S/o / D/o _____ at present _____ (designation) of M/S _____ (name of the Biotechnology unit) certify that the information furnished as above is true and correct to the best of my knowledge and belief.

I hereby undertake to abide by the terms and conditions prescribed under the provisions of Odisha Biotechnology policy, 2024 and its operational guidelines.

I hereby undertake to repay / surrender the assistance, or any part thereof availed with penal interest as decided by the authority-

- i. If the information stated above is found to be false/ incorrect / misleading or misrepresented and there has been suppression of facts / materials or if found to have been disbursed in excess of the amount actually admissible for whatsoever reason.
- ii. If the Quality Certificate is revoked by the authority within five years of obtaining such certificate for any reason.

I hereby certify that this Biotechnology units/Start-ups/Institutes has not applied / sanctioned / availed any amount of assistance under this scheme from any other department of the State Govt. or the Central Govt. or any Financial institution(s) / Support organization in the country and abroad against which the present claim is made.

Copies of relevant documents in support of information / facts furnished above are enclosed herewith.

Signature of the Proprietor / Managing Partner /

Managing Director / Authorised Signatory of

M/s -----

Place-

Date-

List of documents attached

CHECK LIST

Copies of documents to be attached with the application shall be self-attested by
Proprietor / Managing Partner / Managing Director / Authorized Signatory

(Strike out whichever is not applicable)

1	Entrepreneurs Memorandum- II/ IEM / Industrial License / production certificate
2	Power of Attorney / Board Resolution / Society Resolution, as applicable, while signing as Partner / Managing Director / Authorized person.
3	Certificate of registration under Indian Partnership Act 1932 / Societies Registration Act- 1860 / Certificate of incorporation (Memorandum of Association & Article of Association) under Company Act-1956
4	Document in support of date of first investment in fixed capital i.e., land / building / plant & machinery and balancing equipment in respect of Original / Expansion / Modernisation / Diversification
5	Appraisal & approval documents in support of E/M/D as defined in Odisha Biotechnology policy, 2024
6	Statement on fixed asset acquired & installed for Lab. R&D Lab. supported with bills & vouchers
7	Sanction order of loan availed from FI / Banks for the purpose of obtaining equality Certification
8	Quality Certificate / Registration Certificate issued by the competent authority
9	Statement on expenditure incurred for obtaining Quality certification / bills / vouchers / receipt etc.
10	Details of assistance sanctioned / availed so far with sanction order no & date and other supporting documents from State Govt / Central Govt / Govt. Agencies / Financial institutions
11	Undertaking on non-judicial Stamp Paper duly signed by the applicant in the format - Annexure-B1

UNDERTAKING

(Strike out whichever is not applicable)

- I. I / We shall abide by the terms and conditions prescribed under the provisions of Odisha Biotechnology policy, 2024 and its operational guidelines.
- II. I / We shall repay the assistance for Quality Certification or any part thereof with penal interest as decided by the authority-
- III. If the information stated in the application & supporting documents is found to be false/ incorrect / misleading or mis-represented and there has been suppression of facts / materials or if found to have been disbursed in excess of the amount actually admissible for whatsoever reason.
- IV. If the Biotechnology unit goes out of production for a period exceeding six months at a time for any reasons other than labour issues, want of electric power or for the reason which is beyond the control of entrepreneur / management during the period of assistance.
- V. I / we the promoter(s) have not defaulted to Banks / Development Financial Institutions / SIDBI / OSFC / IPICOL / Government and Government controlled agencies in connection with the unit for which the assistance is sought for or for any other unit / activity in the state with which concerned promoter(s) is / are directly or indirectly associated.
- VI. This Biotechnology unit has not applied / availed assistance for quality certification /its renewal in any manner under any other scheme of the State Govt. or the Central Govt. or any Financial Institution(s).
- VII. I / we shall furnish its audited financial statements and other periodical statements of each financial year to the Director, Biotechnology during the period of assistance.

**Signature of the Proprietor / Managing Partner /
Managing Director / Authorised Signatory of**

M/s -----

Place-

Date-